DEPARTMENT OF CORRECTIONS
Division of Adult Institutions
DOC-3428 (Rev. 5/2012)

WISCONSIN

HCV TREATMENT EVALUATION CARE PLAN

PATIENT NAME (Last, First) | DOC NUMBER | DATE OF BIRTH

MR Date _____ ☐ Positive HCV Ab (EIA) Date _____ ☐ HCV educational info given Date _____

☐ Complete DPH Form 4151 Communicable Disease Report Date _____ ☐ Order qualitative HCV PCR Date _____

☐ Negative Qualitative HCV PCR. If negative, order ☐ Repeat PCR in 6 months to verify & **STOP** (Not Infected) Date _____

☐ Positive HCV PCR Date _____ ☐ Is there evidence of both HBV & HAV immunity by history or documentation? ☐ Yes ☐ No

If No, order: ☐ HAV & ☐ HBV vaccines as appropriate

☐ If HIV Positive refer to immunology and follow their recommendations regarding HCV treatment Date _____

☐ Any past HCV Treatment? ☐ Yes ☐ No If Yes, Outcome: _____

☐ Try to establish duration of HCV infection by history: _____

☐ Order HCV f/u appointment in ~ 3-4 months (if new intake) to assess for possible HCV treatment. Or proceed to Step 2.

Step 2 – Hepatitis C Treatment Contraindications (see reverse for further details)

☐ Yes ☐ No Serious concurrent unstable medical condition

☐ Yes ☐ No Severe uncontrolled psychiatric disease especially depression with suicide risk

☐ Yes ☐ No Hypersensitivity to treatment agents

☐ Yes ☐ No Insufficient time to complete treatment (generally 1 year)

☐ Yes ☐ No Currently pregnant

☐ Yes ☐ No Refuses treatment

☐ Yes ☐ No Continuing drug or alcohol use in the last 6 months

If "Yes" was checked for any of the 7 above indications in Step 2, then go to Step 4 monitoring now

Previous genotype 1 patients who were relapsers or partial responders to Peg-intron & Ribavirin Tx may be considered on a case by case basis

Step 3 - Treatment Work-Up: Criteria Met for Tx evaluation

☐ Criteria Met (including psych, CV clearance as indicated on reverse)

Date _____

☐ Obtain Patient Consent for Treatment Date _____

Criteria Not Met

☐ Criteria not met – Date _____

Reason _____

☐ Handout # 3 Initiate Step 4 Monitoring Date _____

☐ Baseline Tests : CBCD, TSH, INR, Cr, Ferritin, Fe sat, ANA, U/A, Uric acid, ALT, AST, TBili, HCV viral load, HCV genotype and recent HIV.
Also: Recent Hep A & B testing (if indicated) and EKG & DFE. HCV genotype _____ HCV Viral Load _____ IU/ml

If patient is viral genotype 1or 4, at least 1 year remains prior to discharge

☐ Yes – proceed with assessment of liver fibrosis

☐ No – go to Step 4 monitoring

HCV viral Genotype 1 or 4, 5, 6

Determine need for liver biopsy: Bx required unless cirrhosis already known to be present, use APRI score to prioritize for bx.

☐ Calculate APRI score (see reverse) _____

☐ Liver Bx results:

Stage _____ Date _____

If Bx ≥ Stage II fibrosis, proceed. If not, go to Step 4 Monitoring

☐ If genotype 1, order the IL 28B genotype test. Date _____

IL 28B genotype Results ☐ CC ☐ CT ☐ TT

☐ File Class III for treatment recommendations from UW and follow protocol as outlined for Genotype 2 or 3 on the right.

HCV viral Genotype 2 or 3

☐ File Class III for treatment recommendations from UW

☐ Denied Date _____ Handout #3 - Initiate Step 4 Monitoring

☐ Approved – Date _____

☐ Obtain Treatment Recommendations from UW Date _____

Step 4 – Monitoring of patients who do not qualify for treatment

☐ Have a plan for each patient, and outline the plan clearly in the Problem List and Progress notes

☐ Ensure baseline HIV, CBCD, INR, ALT, AST, Tbili, alk phos, albumin, Cr, Ferritin, Fe sat, & ANA results are on chart

☐ Obtain ALT, AST, Tbili, Albumin, INR at six month intervals

☐ Obtain CBCD yearly and (if genotype 1) calculate APRI score (see reverse) _____

☐ For patients with past liver biopsies, determine timing of possible re-biopsy. (see reverse for criteria)

☐ Annual review to reassess status of patient regarding possible treatment candidacy.

DISTRIBUTION: Original – Medical Chart, Care Plan Section

EXHIBIT D 000001

STEP 1 – INITIAL EVALUATION FOR HCV Ab+ PATIENTS

For a positive HCV Ab test result:

a) Complete DPH Form 4151 Communicable Disease Report. No need to wait for PCR results, DPH can access PCR data once form is filed.
b) Obtain a new blood specimen for the required confirmatory testing, a HCV Qualitative Polymerase Chain Reaction (PCR) for RNA.
c) This test is sent to the Wisconsin State Laboratory of Hygiene (WSLH).

Note – A negative Qualitative HCV PCR means the patient has cleared the virus, is not infectious, and does not have to be followed for HCV. Counsel and schedule a repeat Qualitative HCV PCR in 6 months to confirm viral clearance (if most recent negative PCR was done at least 6 months after the positive HCV Ab test, it need not be repeated unless a new HCV infection is suspected.)

Immunizations – Assess patient's immunization status to Hepatitis A and B. If susceptible (i.e. not immune by history, previous lab results, or documentation of immunization), schedule immunization series for hepatitis A or B or both with Twinrix series of three.

□ If HIV Positive refer to immunology and follow their recommendations regarding HCV treatment

STEP 2 – HEPATITIS C TREATMENT CONTRAINDICATIONS & SCREENING EVALUATIONS

(1) Serious concurrent unstable medical conditions

- History of solid organ transplant (renal, heart, or lung)
- Certain autoimmune disorders, e.g. autoimmune hepatitis
- Uncontrolled endocrine disorders, e.g. diabetes, thyroid disease
- Serious concurrent medical diseases, such as severe: hypertension, heart failure, coronary heart disease, COPD
- Decompensated cirrhosis (bili ≥ 1.5, INR ≥ 1.5, alb < 3.5, ascites, hepatic encephalopathy)
- Platelet count <75,000/mm3 or ANC <1,500 cells/mm3
- Documented non-adherence to prior therapy, or failure to complete pretreatment evaluation process

(2) Severe uncontrolled psychiatric disease, particularly unstable Axis I diagnosis and depression with current suicidal risk.
(3) Hypersensitivity to minimum required treatment agents (interferon, ribavirin.)
(4) Continuing illicit drug use or alcohol use in the last 6 months.
(5) Patient will be incarcerated for an insufficient period of time to complete treatment.

- At least 1 year LOS needed at time of Step 2 assessment - Evaluation and treatment completion takes up to 12 months

(6) Pregnant. Re-evaluate when no longer pregnant.
(7) Patient refuses evaluation or treatment. See Consent/Refusal to Hepatitis C Treatment (DOC-3429).

□ **If any one of the above seven conditions are present, then STOP.** No further HCV testing (ie HCV viral load or genotype) is indicated at this time. See Step 4 Monitoring. Develop a medical monitoring plan and address pertinent medical issues. If conditions change, reconsider for HCV treatment.

□ Previous genotype 1 patients who were relapsers or partial responders to Peg-intron & Ribavirin Tx may be considered for triple therapy on a case by case basis. There are currently no plans to re-treat any genotypes 2, 3, or 4 who did not have successful previous treatments.

□ Psychiatric clearance for past or present mental health issues. A psychiatrist needs to complete a DOC-3453 for any patient with an MH-2 classification, & any patient on psychiatric meds for a psychiatric diagnoses.

□ ECG for patients with preexisting cardiac disease
□ Exercise stress Test if ≥ age 45 or if ≥ 30 with FHx of premature coronary artery disease
□ Cardiac risk assessment is critical because hemolysis associated with ribavirin may precipitate angina pectoris

STEP 3 TREATMENT WORK-UP

□ Obtain informed consent □ Quantitative HCV PCR & viral genotype from DOC Contracted Laboratory □ Baseline Tests as noted on reverse.

□ **Viral Genotype 1 or 4, 5, 6** Compute **APRI** score: {(AST ÷ lab upper limit of normal for AST) x 100} ÷ {platelet count ÷ 1,000}
□ Inmates who have an **APRI** of < 0.5 are lower priority for biopsy; inmates who have an **APRI** of ≥ 0.5 are higher priority for biopsy—with the higher the **APRI**, the higher the priority for biopsy.
□ **Viral Genotype 1 –** IL 28B human genotype results will be used by UW for prognostic purposes.

□ **Viral Genotype 2 or 3 –** Obtain Class III for treatment recommendations from UW. If denied, counsel patient and initiate Step 4 – monitoring. If approved, obtain and initiate treatment recommendations

□ **Other Viral Genotypes –** Uncommon in our population; contact UW Hepatology for recommendations re: genotype & submit Class III for approval

STEP 4 MONITORING - Have a plan for each patient: Outline the plan clearly on the Problem List/Progress Notes

□ **Hepatocellar carcinoma monitoring**: The risk for development of hepatocellular carcinoma does not begin until the development of cirrhosis has occurred. Therefore neither AFP nor liver U/S or CT are indicated unless cirrhosis is known or strongly suspected. If so, perform AFP & U/S yearly

□ **Labs: Serum ammonia** levels have no prognostic value outside of making a diagnosis of delirium, and should be avoided.
HCV viral loads and genotyping are not necessary unless treatment is indicated.

□ **Repeat liver biopsies**: Determination of timing of a re-biopsy for those patients whose treatment was deferred due to having < Stage II fibrosis on previous biopsy should be based on subsequent increases in the **APRI** score and/or evidence of steatosis or inflammation. Those who develop clinical evidence of hepatic dysfunction should also be priority candidates for re-biopsy.

□ **Annual review** to assess patient status as regards both potential treatment candidacy and overall status of patient's liver function and related health issues.

DISTRIBUTION: Original -- Medical Chart, Care Plan Section